



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/824,984	04/02/2001	Sharat Singh	0225-0033.25	2489

22918 7590 01/02/2003

PERKINS COIE LLP
P.O. BOX 2168
MENLO PARK, CA 94026

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
----------	--------------

1637

DATE MAILED: 01/02/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/824,984

Applicant(s)
Singh et al.

Examiner
Joyce Tung

Art Unit
1637



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 22, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-25 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 23 6) ☐ Other:

Art Unit: 1637

Response to Amendment

1. The amendment filed 7/22/2002 has been entered.
2. Every rejection in the Office action mailed 3/27/2002 is withdrawn because of the amendment and argument filed in the response, 7/22/2002.

NEW GROUNDS OF REJECTIONS

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 5-25 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitations of claims 5-25 are not clearly supported in the specification because the terms/phase as listed on page 13-15 of the preliminary amendment filed 7/22/2002 can not be found on the page as indicated. Thus, it constitutes new matter. Clarification is required.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1637

6. Claims 5-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 10-13 are vague and indefinite because of the language "wherein upon cleavage M and D impart on said eTag reporter a distinct mass/charge ratio". It is unclear whether or not there are two cleavages in which one is the cleavable linkage between the eTag reporter and the antibody binding compound and the another is on the mobility modifier and the detection group. Clarification is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 5-6, 9 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bocuslaski et al. (4,331,590).

Bocuslaski et al. disclose a specific binding assay involving employing an enzyme-cleaving substrate label in the formation of the labeled conjugate (See column 2, lines 5-9). The labeled conjugates comprise an enzyme-substrate portion, an indicator portion in which the conjugate is cleavable by an enzyme to produce a detectable indicator product (See column 2,

Art Unit: 1637

lines 5-18) and binding components for antibody (See column 11, lines 24-25). This teaching anticipates that there is antibody binding compound on the labeled conjugates. A linking group through which the dye indicator is covalently bound to the binding component of the conjugate and cleaving enzyme is to cleave the glycosidic linkage (See column 2, lines 33-36). The assay is adaptable to the detection of any specifically bindable ligand and is particularly useful in the detection of haptens, including antibodies (See column 2, lines 40-43 and column 8, lines 39-62). The label is fluorescence (See column 5, lines 10-39 and column 6, lines 1-10). The separation step can be involved such conventional techniques (See column 10, lines 60-67). The detectable dye product is distinguishable from the intact labeled conjugate and fluorometrically or colorimetrically active (See column 5, lines 18-39). Thus the teachings of Bocuslaski et al. anticipate the limitations of claims 5-6, 9 and 18.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

Art Unit: 1637

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bocuslaski et al. (4,331,590) as applied to claims 5-6, 9 and 18 above, and further in view of Kameda et al (4,780,421).

The teachings of Bocuslaski et al. are set forth in section 8 above and do not disclose said cleavable linkage is cleavable by oxidation and the linkage is selected from the group consisting of olefins, thioethers, sulfoxides and so on as listed in claims 7-8.

Kameda et al. disclose an improvement in an assay which relies on the detection of a labeled, solubilized specific binding complex. The complex is labeled through a cleavable linkage (See the abstract). The linkage is disulfide, thioether or amide (See column 6, lines 24-28). The linkage is cleaved with reducing agent (See column 9, lines 33-37). Dihydroxy moiety is cleaved by periodate (See column 6, lines 29-33) (which is oxidation).

One of ordinary skill in the art at the time of the instant invention would have been motivated to apply the linker of Kameda et al. to the labeled conjugate of Bocuslaski et al. because the method of Kameda et al. is an improvement in an assay involving a bond cleavable which permits an increase in the sensitivity of these assays, as well as contributing to the ease

Art Unit: 1637

performance (See column 2, lines 54-58). It would have been prima facie obvious to carry out the method as claimed..

11. Claims 10-17, and 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bocuslaski et al. (4,331,590) as applied to claims 5-6, 9 and 18 above, and further in view of Giese (Analytical Chemistry, 1983, Vol. 2(7) page 166-168) and Breslow et al. (6,331,530).

The teachings of Bocuslaski et al. are set forth in section 8 above and Bocuslaski et al. do not address a cleaving agent is a sensitizer which generates an active species, singlet oxygen or said sensitizer which is capable of generating singlet oxygen when photoactivated as recited in claims 14-15.

Breslow et al. disclose a linker between two β -cyclodextrin molecules and that a photosensitizer is encapsulated within a matrix, wherein the cleavable linker is cleaved upon exposure to light (See the abstract). Singlet oxygen is produced to cleave the linker (See column 3, lines 47-51).

Bocuslaski et al. do not disclose the labeled conjugate which has a mobility modifier as claimed in claim 10 but any molecule compound has mobility and based upon the labeled conjugate, there are 1-500 atoms selected from the group as listed in claim 10 (See column 5, lines 54-65). This teaching suggests that the labeled conjugate has mobility modifier.

Bocuslaski et al. do not disclose a second antibody binding compound used in the method as recited in claim 14. However, Bocuslaski et al. disclose several labeled conjugates for detecting several different ligands used in the assay (See column 13, lines 23 to column 18,

Art Unit: 1637

lines 25). Thus one of ordinary skill in the art would have been motivated to have an additional labeled conjugate as needed. In addition Bocuslaski et al. do not disclose the second antibody binding compound having a sensitizer for generating an active species to cleave the cleavable linkage as recited in claim 19. Since it is unclear what is meant by the phrase "a sensitizer", although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims, the teachings of Bocuslaski et al. suggest the limitations of claim 19.

Bocuslaski et al. do not disclose electrophoretically separating and identifying the one or more released eTag reporters to determine the presence or absence of the one or more target compounds as recited in claim 19

Giese disclose an electrophoric release tag which has the same components as the e-tag probe. The release tags comprise 3 molecular groups, known as 'signal', 'release' and 'reactivity' groups. The release group provides a site for specific covalent cleavage and the reactivity group attaches the release tag to a substance of interest (See pg. 166, column 1, first paragraph). Giese also addresses the benefit of using the tag (See pg. 166, column 1, third paragraph to column 2, first paragraph) and the potential usefulness in which the tag can be used for detecting antigen or haptens and the tag can be used for detecting several target simultaneous in a give sample (See pg. 167, column 1, second paragraph). The teachings of Giese suggest that the reactivity group of the tag must have an antibody binding compound. The released tags are applied to gas chromatography (See pg. 166, column 1, second paragraph) and the released tags

Art Unit: 1637

can be developed numerous tags with different gas-phase properties which can be measured as series of chromatographic peaks (See pg 166, column 1, last paragraph to pg. 167, column 2, first paragraph)

One of ordinary skill in the art at the time of the instant invention would have been motivated to modify the method of Bocuslaski et al. by applying a second binding compound having a sensitizer for generating an active species for detecting the presence or absence one or more target compounds as claimed with a reasonable expectation of success because the labeled conjugate as taught by Bocuslaski et al. (See column 9 to column 10) or the electrophoric release tag as taught by Giese is very useful in the detection of one or more target compounds (See pg. 166, column 1, third paragraph to column 2, first paragraph and pg. 167, column 1, second paragraph). The photolabile cleavable linkage as taught by Breslow et al. is photosensitizer and can produce singlet oxygen when photoactivated because the active cleaving agent, singlet oxygen is used in the system for cancer therapy and this suggests that the active cleaving agent must be very efficient. Thus, an ordinary skill in the art would have combined the teachings of the references to carry out the instant invention as claimed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1637

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.


Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

Art Unit: 1637

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

December 20, 2002


GARY BENZION, PH.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600